

Development of Microbial Risk Assessment Methods

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The Agency needs relevant methods for assessing microbial risks. Numerous questions arise as we adapt traditional risk assessment methods and develop new approaches appropriate for the unique characteristics of microbial agents. Collaborative efforts are being undertaken across the Agency, with universities and other federal agencies to compile and assess methods to determine (1) how human disease risk can be estimated for specific pathogens in susceptible population groups, (2) how transmission rates can be utilized to estimate human disease risk from multiple source exposures, and (3) how pathogen virulence factors and structural activity relationships can be valued in microbial assessments.

NCEA scientists are building on existing microbial risk frameworks to handle data gaps in dose-response, epidemiological or clinical information, human population susceptibility differences, multiple-source pathogen exposures, primary and secondary transmissions, and variable pathogen virulence factors. NCEA scientists have been actively collaborating with other U.S. Environmental Protection Agency (U.S. EPA) scientists, other federal agencies, and with the scientific communities to gain broad perspectives in addressing these microbial risk issues. The following are examples of those activities.

NCEA scientists are working with the Food and Drug Administration (FDA) National Center for Toxicological Research (NCTR) on ongoing experimental animal work with the protozoan parasite *Cryptosporidium parvum* to quantify primary and secondary transmission rates, dose-response, and disease course and outcomes in animal subgroups representing healthy and compromised-human population groups. NCEA scientists have also been working with Dr. James Englehardt (University of Miami) in developing predictive Bayesian dose-response models for the low-dose exposure range. Model development is ongoing with limited available data. Another example of collaborative efforts is the secondary transmission work undertaken as cooperative agreements with the University of California and the University of Michigan.

Because certain human diseases are due to exposures to preformed microbial toxins, such as water or food-borne cyanotoxin produced by Cyanobacteria, NCEA scientists in collaboration with the U.S. EPA National Exposure Research Laboratory (NERL) scientists are looking at exposure risk and developing a toxicity review for three to four cyanotoxins. Quantitative and qualitative Structural Activity Relationship (SAR)/Quantitative Structural Activity Relationship

(QSAR) models are being developed to support microbial toxin risk assessments. The results of the work described above will be applied to microbial risk and exposure assessments to support the Long Term Surface Water Treatment Rule and the Ground Water Rule.

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